

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION**

GALDERMA LABORATORIES, L.P.	§	
and GALDERMA S.A.,	§	
Plaintiffs,	§	
	§	
	§	
v.	§	CIVIL ACTION NO. _____
	§	
	§	
PERRIGO CO. and PERRIGO ISRAEL PHARMACEUTICALS LTD.,	§	
	§	
	§	
Defendants	§	Jury Trial Requested

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, GALDERMA LABORATORIES, L.P. (“Galderma L.P.”) and GALDERMA S.A. (“Galderma S.A.”), file this Complaint For Patent Infringement against defendants Perrigo Co. and Perrigo Israel Pharmaceuticals Ltd. (collectively, “Defendants”), and state:

INTRODUCTION

1. This is a civil action for patent infringement in violation of the United States Patent Act, 35 U.S.C. § 271, et seq.

2. This suit stems from Defendants’ submitting of Abbreviated New Drug Application No. 90-974, including any amendments (collectively, “the ANDA”), with the United States Food and Drug Administration (the “FDA”) pursuant to 21 U.S.C. § 355.

PARTIES

3. Galderma L.P. is a Texas limited partnership, with its principal business address at 14501 N. Freeway, Fort Worth, Texas 76177. Galderma L.P. is the beneficial holder of rights to market CLOBEX® Shampoo (clobetasol propionate shampoo (0.05%)) (hereafter “Clobex® Shampoo”) under FDA approval of New Drug Application No. 21-644 approved February 5,

2004. Galderma L.P. has the exclusive right from Galderma S.A. to distribute Clobex® Shampoo in the United States.

4. Galderma S.A. is a Swiss corporation, with its principal business address at World Trade Center, Avenue de Gratta-Paille, Case Postale 453, CH-Lausanne 30, Switzerland. Galderma S.A. owns United States Patent No. 7,316,810 (“the ‘810 Patent”) and United States Patent No. 7,700,081 (the “‘081 Patent). A copy of the ‘810 Patent is attached as Exhibit “A.” A copy of the ‘081 Patent is attached as Exhibit “B.”

5. On information and belief, Perrigo Co. (“Perrigo Co.”) is a Michigan corporation, having a principal place of business located at 515 Eastern Avenue, Allegan, Michigan 49010, and is engaged in the manufacture and sale of pharmaceutical products.

6. On information and belief, Perrigo Israel Pharmaceuticals Ltd. (“Perrigo Israel”) is an Israeli corporation, having a principal place of business located at 29 Lehi Street, Bnei Brak 51200, Israel. On information and belief, Perrigo Israel manufactures bulk pharmaceutical products.

7. On information and belief, Perrigo Israel is a wholly-owned subsidiary of Perrigo Co.

8. On information and belief, Perrigo Israel is controlled by and/or is an agent of Perrigo Co.

9. On information and belief, Perrigo Israel conducts its North American operations, in part, through Perrigo Co.

JURISDICTION AND VENUE

10. This is a complaint for patent infringement and for declaratory judgment of patent infringement. This Court has jurisdiction over the subject matter of the claims asserted pursuant to 28 U.S.C. §§ 1331 and 1338, as well as 28 U.S.C. §§ 2201 and 2202. Venue in this Court is proper under 28 U.S.C. §§ 1391 and 1400(b).

11. Upon information and belief, Perrigo Co., as reported in its 2009 Annual Report, engages in the manufacture and sale of a range of generic pharmaceutical products within the United States generally and the State of Texas specifically, including to Wal-Mart, CVS, Kroger, Safeway, Dollar General, Sam's Club, Costco and Walgreens pharmacy stores within this District.

12. Perrigo Co. is an authorized agent for Perrigo Israel for communications with the FDA regarding the ANDA, which purposefully targets a Texas Limited Partnership within the District and which gives rise to the instant litigation.

13. Perrigo Co. is subject to personal jurisdiction in this District by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of Texas law, its substantial and continuing contacts with the State, and its knowledge that a Texas Limited Partnership located in this District would be injured by its actions.

14. Upon information and belief, Perrigo Israel, as reported in its 2009 Annual Report, engages in the manufacture and sale of a range of generic pharmaceutical products purposefully availed to the United States generally and the State of Texas specifically, including sales to Wal-Mart, CVS, Krogers, Safeway, Dollar General, Sam's Club, Costco and Walgreens pharmacy stores within this District.

15. On information and belief, Perrigo Israel, according to Perrigo Israel's profile in Dun & Bradstreet Israel Ltd., develops and manufactures generic topical drugs for the U.S. market.

16. On information and belief, Perrigo Israel, according to its Corporate Profile, develops and manufactures generic topical drugs at its Yeruham, Israel manufacturing location for the U.S. market as part of the Perrigo Rx Pharmaceuticals Group. On information and belief, Perrigo Israel filed the ANDA to obtain FDA approval to sell generic clobetasol propionate shampoo 0.05% into the U.S. market.

17. On information and belief, Perrigo Co. distributes and/or sells drugs developed and manufactured by Perrigo Israel for the U.S. market.

18. On information and belief, Perrigo Israel regularly ships generic pharmaceuticals to Perrigo Co. from locations outside the United States for distribution by Perrigo Co. within the United States generally, and within this District.

19. Perrigo Co.'s acts and contacts with this District, as a distributor for Perrigo Israel, are attributable to Perrigo Israel for jurisdictional purposes.

20. Perrigo Israel also filed the ANDA (an act of infringement under 35 U.S.C. § 271(e)(2)) for the infringing product and issued a certification under 21 U.S.C. § 355(j)(2)(B) (the "Paragraph IV Certification") – the acts which give rise to the instant litigation – with knowledge that Galderma L.P. would be injured by such actions in this district, and delivered its Paragraph IV Certification to Galderma L.P. in this district.

21. Perrigo Israel is subject to personal jurisdiction in this District by virtue of, *inter alia*, its specific contacts with a Texas Limited Partnership within the District giving rise to the instant litigation, its conduct of business in this District, its purposeful availment of the rights

and benefits of Texas law, its substantial and continuing contacts with the State, and its knowledge that a Texas Limited Partnership located in this District would be injured by its actions.

22. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(c) and 1400(b). For example, Plaintiff Galderma Laboratories, L.P. is located in this District, and Galderma's witnesses and documents will be material to this litigation. As another example, venue is appropriate in this District because the claims asserted herein arise out of an act of patent infringement (i.e., Perrigo Co. and Perrigo Israel's filing of the ANDA and issuance of the Paragraph IV Certification) purposefully targeting a resident of this District (Galderma Laboratories, L.P.). As a further example, 21 U.S.C. § 355(j)(5)(C)(i)(II) establishes this District as the only proper venue in which Perrigo Co. and Perrigo Israel could file suit seeking a declaration of non-infringement in connection with the ANDA. Finally, Perrigo Co. and Perrigo Israel have consented to both personal jurisdiction and venue in this district in a related case involving another Clobex® product, styled *Galderma Laboratories, L.P. and Galderma, S.A. v. Perrigo Co. and Perrigo Israel Pharmaceuticals Ltd.*, Civil Action No. 3:09-cv-02322-M.

BACKGROUND FACTS

A. The ‘810 Patent

23. On November 13, 2000, Isabelle Preuilh, Anne-Emmanuelle Guise, and Nathalie Willcox (inventors) and Galderma S.A. (assignee) filed an application with the United States Patent and Trademark Office (“USPTO”), namely United States Patent Application Serial No. 09/709,477 (“the ‘477 Application”) entitled ‘Foaming Composition For Washing and Treating Hair and/or Scalp Based on an Active Principle.” On January 8, 2008, based on the ‘477 Application, the USPTO issued the ‘810 Patent.

24. The ‘810 Patent is valid, enforceable, and has not expired.
25. Isabelle Preuilh, Anne-Emmanuelle Guise, and Nathalie Willcox assigned their rights to and interest in the ‘477 Application and the ‘810 Patent to Galderma S.A.

B. The ‘081 Patent

26. On June 16, 2006, Isabelle Preuilh, Anne-Emmanuelle Guise, and Nathalie Willcox (inventors) and Galderma S.A. (assignee) filed another application with the USPTO, namely United States Patent Application Serial No. 11/453,936 (“the ‘936 Application”) entitled “Foaming Composition For Hair Care.” On April 20, 2010, based on the ‘936 Application, the USPTO issued the ‘081 Patent.

27. The ‘081 Patent is valid, enforceable, and has not expired.
28. Isabelle Preuilh, Anne-Emmanuelle Guise, and Nathalie Willcox assigned their rights to and interest in the ‘936 Application and the ‘081 Patent to Galderma S.A.

C. Clobex® Shampoo

29. On February 5, 2004, Galderma L.P. obtained FDA approval to market Clobex® Shampoo. The ‘810 Patent and the ‘081 Patent are listed in the FDA’s Approved Drug Products list (the “Orange Book”) as reading on Clobex® Shampoo.

30. Galderma S.A. has granted Galderma L.P. the exclusive right to distribute Clobex® Shampoo in the United States.

D. Defendants’ Infringement

31. On information and belief, Defendants reviewed the ‘810 Patent and the ‘081 Patent and certain commercial and economic information relating to Clobex® Shampoo, including estimates of the revenues generated by the sale of Clobex® Shampoo, and decided to

file the ANDA seeking approval to market generic clobetasol propionate shampoo 0.05% ("the Accused Product").

32. On information and belief, Defendants submitted the ANDA to the FDA to seek approval to engage in the commercial manufacture, use, and sale of clobetasol propionate shampoo 0.05% prior to the expiration of the '810 Patent and the '081 Patent. The generic clobetasol propionate shampoo 0.05% that is the subject of the ANDA directly and indirectly infringes the '810 and '081 Patents.

33. Plaintiffs received a letter dated July 6, 2010 from Defendants notifying them that Perrigo Co. and Perrigo Israel's ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Defendants' opinion, the '810 Patent and the '081 Patent are invalid or not-infringed.

34. On information and belief, Defendants were necessarily aware of the '810 Patent and the '081 Patent when they filed ANDA No. 90-974 and the Paragraph IV certification.

35. Plaintiffs commenced this action within 45 days of the date that they received Defendant's notice of ANDA No. 90-974 containing the Paragraph IV certification.

36. On information and belief, Defendants intend to continue seeking approval of ANDA No. 90-974 from the FDA and to engage in the commercial manufacture, marketing and sale of clobetasol propionate shampoo 0.05% (including commercial marketing and sale of such a product in the State of Texas, including this District) in the event that FDA approves ANDA No. 90-974.

COUNT I
(PATENT INFRINGEMENT)

37. Plaintiffs incorporate paragraphs 1 through 36 above by reference as if fully set forth herein.

38. 35 U.S.C. § 271(e)(2)(A) provides:

It shall be an act of infringement to submit . . . an application under section 355(j) of title 21 or described in section 355(b)(2) of title 21 for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

39. The ‘810 Patent and the ‘081 Patent are valid, enforceable, and have not expired.

Also, the Accused Product and its use as directed fall within the literal scope of the claims of the ‘810 Patent and the ‘081 Patent and/or infringes the ‘810 Patent and the ‘081 Patent under the doctrine of equivalents. As such, Defendants infringed the ‘810 Patent and the ‘081 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ‘810 Patent and the ‘081 Patent

40. As a result of Defendants’ infringement, Plaintiffs are entitled to a declaration that (a) ‘810 Patent and the ‘081 Patent valid and enforceable, and (b) the Accused Product infringes the ‘810 Patent and the ‘081 Patent if made, used as directed, sold or offered for sale during the term of the ‘810 Patent and the ‘081 Patent.

41. As a result of Defendants’ infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Defendants and all those in privity with or acting in concert with Defendants from manufacturing, selling, or offering the Accused Product for sale during the term of the ‘810 Patent and the ‘081 Patent, or from otherwise infringing or inducing the infringement of the ‘810 Patent and the ‘081 Patent.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury of all issues and claims alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs hereby pray for the following relief:

- (A) A declaration that the '810 Patent and the '081 Patent are valid and enforceable;
- (B) A declaration, pursuant to 35 U.S.C. § 271(e), that Defendants have infringed the '810 Patent and the '081 Patent by submitting the ANDA;
- (C) A declaration, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the ANDA is not to be earlier than the expiration date of the '810 Patent and the '081 Patent;
- (D) A permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, enjoining Defendants and their officers, agents, servants, employees, privies, and others acting for, on behalf of, or in concert with any of them from manufacturing, importing, selling, or offering the Accused Product for sale, or from otherwise infringing or inducing the infringement of the '810 Patent and the '081 Patent;
- (E) An award to Plaintiffs, pursuant to 35 U.S.C. § 271(e)(4)(C), of damages and other monetary relief, including enhanced damages, as a result of Defendants' infringement, to the extent there has been any commercial manufacture, use, import, offer to sell, or sale within the United States or importation into the United States of the Accused Product prior to expiration of the '810 Patent and the '081 Patent;
- (F) A declaration that this is an exceptional case and an award, pursuant to 35 U.S.C. §§ 271(e)(4) and 285, granting Plaintiffs their costs and attorneys' fees in pursuing this case; and
- (G) Such other and further relief as this Court may deem just and proper.

Respectfully submitted,

/s/ Michael C. Wilson

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